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BACHMAN & LAPOINTE, P.C.
900 CHAPEL STREET
SUITE 1201
NEW HAVEN, CT 06510

EXAMINER	
BELLAMY, TAMIKO D	

ART UNIT	PAPER NUMBER
2856	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,382	HERMET ET AL.	
	Examiner	Art Unit	
	TAMIKO D. BELLAMY	2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 December 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 25-28, and 33 objected to because of the following informalities:

   a. Claims 25-28, change "millitres" to -- milliliters--.

   b. Claim 33, change "millitre" to -- milliliter--.

2. Appropriate correction is required.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: **6 (See fig. 1).** Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, **a tap and a stopper pierced by a**

needle or screw-fitting sealed by a stopper must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, **a breakable fitting, and a tap or a tubing clip** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 24, 29-32, 34-37, 39- 42, 44, and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al. (2003/0013199).

Re claim 24, a depicted in figs. 3 and 4, Anderson et al. discloses drawing n samples from n different containers (e.g., sample sources A-E in baths (303, 307, 311, 315, and 319)). As depicted in fig. 4, Anderson et al. discloses placing the each sample drawn respectively in an intermediate sampling chamber (e.g., extraction modules (301, 305, 309, 313, and 317) each having a mini-reservoir (401) (Pg. 9, Pars. 108-109). Anderson et al. discloses transferring identical volumes of each sample drawn into a common mixer (e.g., mixer (239)) (Pg., Par. 110). Anderson et al. analyzing the samples (Pars. 24-25, 105, and 131).

Re claim 29, as depicted in fig. 3, Anderson et al. discloses transferring the drawn samples (e.g., samples A-E) into a mixing chamber (e.g., mixer 2 (329)) is initiated by an external action (switching valve SV1) (Pg. 8, Par. 97).

Re claim 30, Anderson et al. discloses samples drawn in to a mixer (329) automatically (Pg. 1, Par. 3).

Re claim 31, Anderson et al. discloses performing in a sterile manner (e.g., clean room) (Pg., 7, Par. 74).

Re claim 32, as depicted in fig. 3, Anderson et al. discloses transferring a given volume of the mixture sample to be analyzed to an analysis device (Pg. 9, par. 105).

Re claim 34, Anderson et al. discloses performing in a sterile manner (e.g., clean room) (Pg., 7, Par. 74). Anderson et al. also discloses transferring a given volume of the mixture sample to be analyzed to an analysis device (Pg. 9, par. 105). Therefore, the transfer to the analysis device is aseptic.

Re claim 35, as depicted in figs. 3 and 4, Anderson et al. discloses at least one intermediate sampling chamber (e.g., mini-reservoir (401)) being connected to transfer to a mixing chamber (329) at least part of the sampled liquid (Pg. 8, Par. 97).

Re claim 36, as depicted in fig.3, Anderson et al. discloses the mixing chamber (329) is disposed under the sampling chambers (301, 305, 309, 313, and 317).

Re claim 37, as depicted in fig. 3, Anderson et al. discloses the mixer (329) is associated in a removable manner with the sampling devices (See conduits (327) connected to valves (SV1, and valve at lower end of conduit (327) connected to the mixer (329)).

Re claim 39, as depicted in fig. 3, Anderson et al. discloses a tubing (e.g., conduit (327, 323)) between the sampling chambers (301, 305, 309, 313, and 317) and the mixer (329) and a breakable fitting (e.g., valves (SV1)) and valve ant end of conduit (327) connected to mixer (329).

Re claim 40, Anderson et al. discloses a stopper (e.g., see valve connected at the entrance of the mixer (329)).

Re claim 41, as depicted in fig. 3, Anderson et al. discloses at least one non-return valve (Par. 87, 97).

Re claim 42, Anderson et al. discloses the instrument is implemented in materials compatible with a clean room manufacturing environment a sterile manner (Pg., 7, Par. 74).

Re claim 44, Anderson et al. discloses connecting the drawing and mixing device to an analysis device (Pg. 9, Par. 105).

Re claim 45, Anderson et al. discloses performing in a sterile manner (e.g., clean room) (Pg., 7, Par. 74). Anderson et al. also discloses transferring a given volume of the mixture sample to be analyzed to an analysis device (Pg. 9, par. 105). Therefore, the transfer to the analysis device is aseptic.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 25-28, 33, 43, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (2003/0013199).

Re claims 25 and 27, Anderson et al. discloses drawing a precisely measured portion of an original sample to mixer (329) (Pars. 97 and 99). **While Anderson et al. does not**

specifically discloses drawing a volume between 0.5 and 20 milliliters, Anderson et al. specifically states that when enough liquid is in reservoir (401) of the extraction device (301) the valves (403 & 405) are closed, stopping the liquid draw (Par. 108-111). Anderson et al. also discloses that the device is operated by computerized control. Therefore this teaching clearly infers and/or suggests entering a predetermined volume of liquid to be drawing within the computer. The computer can easily be manipulated to define drawing a volume of liquid between 0.5 and 20 mL as claimed. Therefore, to employ Anderson et al. on a drawing a liquid between 0.5 and 20 mL would have been obvious to one of ordinary skill in the art at the time of the invention since this reference explicitly teaches operating the device by a computerized control.

Re claims 26 and 28, Anderson et al. discloses drawing a precisely measured portion of an original sample to mixer (329) (Pars. 97 and 99). **While Anderson et al. does not specifically discloses drawing a volume between 2 and 8 milliliters**, Anderson et al. specifically states that when enough liquid is in reservoir (401) of the extraction device (301) the valves (403 & 405) are closed, stopping the liquid draw (Par. 108-111). Anderson et al. also discloses that the device is operated by computerized control. Therefore this teaching clearly infers and/or suggests entering a predetermined volume of liquid to be drawing within the computer. The computer can easily be manipulated to define drawing a volume of liquid between 0.5 to 20 mL as claimed. Therefore, to employ Anderson et al. on a drawing a liquid between 0.5 and 20 mL would have been obvious to one of ordinary skill in the art at the time of the invention since this reference explicitly teaches operating the device by a computerized control.

Re claim 33, Anderson et al. discloses drawing a precisely measured portion of an original sample to mixer (329) (Pars. 97 and 99). **While Anderson et al. does not specifically discloses transferring a minimum volume of 1 milliliter of the mixture sample**, Anderson et al. specifically states that when enough liquid is in reservoir (401) of the extraction device (301) the valves (403 & 405) are closed, stopping the liquid draw (Par. 108-111). Anderson et al. also discloses that the device is operated by computerized control. Therefore this teaching clearly infers and/or suggests entering a predetermined volume of liquid to be drawing within the computer. The computer can easily be manipulated to transfer 1 mL of mixed sample as claimed. Therefore, to employ Anderson et al. on transferring 1 mL of mixed sample would have been obvious to one of ordinary skill in the art at the time of the invention since this reference explicitly teaches operating the device by a computerized control.

Re claim 43, Anderson et al. discloses the device implement in a clean room manufacturing environment (Par. 74). While Anderson does not specifically disclose the drawing and mixing device can be sterilized by β or y irradiation, the clean room provides a sterile environment. Kleinsek discloses that it is known in the art to have a clean room with UV irradiation. Therefore, to modify Kleinsek by employing sterilizing by irradiation would have been obvious to one of ordinary skill in the art at the time of the invention since Kleinsek teaches a known art that makes use of a clean room with UV irradiation . The skilled artisan would be motivated to combine the teachings of Anderson et al. and Kleinsek since Anderson states that his invention is applicable to placing a device inside of a sterile clean room and Kleinsek is only used to show that it is

know to uses a clean room with UV irradiation. Therefore placing the device a clean room with UV irradiation would provide the same end result of sterilizing the device of Anderson et al. with irradiation.

Re claim 46, as depicted in fig. 4, Anderson et al. discloses a sampling chamber (e.g., mini-reservoir (401). While Anderson et al. does not specifically disclose that the sampling chamber consist of flexible plastic material, the court held in In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), that selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. Therefore, to employ Anderson et al. on a sampling chamber that consist of flexible plastic material would have been obvious to one of ordinary skill in the art at the time of the invention since this reference explicitly teaches sample reservoir made from a predetermined material.

10. Claim 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (2003/0013199) in view of Gleizes (FR2784023A1).

Re 38, as depicted in figs. 3 and 4, Anderson et al. discloses the connection between the containers (303, 307, 311, 315, and 319) and the sampling chambers (e.g., extraction modules (301, 305, 309, 313, and 317) including mini-reservoirs (401)) comprise tubing (e.g., conduit 321) (Par. 95). Anderson et al. lacks the detail of a connection between the containers and the sample chambers comprises tubing, tap and a stopper that can be pierced by a needle. Gleizes discloses a container (1) for a medical sampler having a sealable stopper (2) with a closable hole (4) receiving an extraction tube (suction tube (6). As depicted in fig. 2, the stopper includes a tap (e.g., combination of

spout (40) and closable hole (4) that function as a spout and a valve). Therefore, to modify Anderson et al. by employing tap and a stopper would have been obvious to one of ordinary skill in the art at the time of the invention since Gleizes teaches a sampling container that includes a sealable stopper. The skilled artisan would be motivated to combine the teachings of Anderson et al. and Gleizes since Anderson states that his invention is applicable to medical and Gleizes is directed to a medical sample in a container used for analysis and the containers provides the added limitation of a tap and a stopper.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAMIKO D. BELLAMY whose telephone number is (571)272-2190. The examiner can normally be reached on Monday - Friday 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tamiko Bellamy
/TB/
February 3, 2009
/Hezron Williams/
Supervisory Patent Examiner, Art Unit 2856